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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,802	09/17/2001	Roland Kreutzer	33796	8835

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EXAMINER

LACOURCIERE, KAREN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 06/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/889,802

Applicant(s)

KREUTZER ET AL.

Examiner

Karen A. Lacourciere

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 221-225, 232-239, 241-245 and 247-254 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 221-225, 232-239, 241-245 and 247-254 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03-23-2004 has been entered.

Claims 221-225, 232-239, 241-245 and 247-254 are pending examination.

Specification

The amendment filed 04-20-2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicant has added a summary of the invention that includes a description of the invention wherein the oligoribonucleotides comprise a 3'-overhang, including a single base overhang. No support could be found for these aspects of the invention in the originally filed specification or claims and they are considered to be new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The rejection of record of claim 249 is rejected under 35 U.S.C. 112, second paragraph is withdrawn in response to Applicant's amendment filed 03-23-2004.

However, new rejections under 35 USC 112, second paragraph are set forth below.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 221-225, 236-239, 241-245, 247, and 249-252 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 221 and claims dependent on claim 221 are indefinite because it is unclear what structure is being claimed. The claim recites an oligoribonucleotide that consists of various elements, but it is unclear what the elements are, for example, does the oligoribonucleotide consist of two separate RNA strands and a self-complementary double stranded structure and a dsRNA and a 3' overhang (which is not consistent with Applicant's arguments or specification), or does the oligoribonucleotide consist of the two separate RNA strands wherein the two strands consist of self-complementary double stranded structure and a dsRNA and a 3' overhang? Is there a double stranded structure and a dsRNA or is the (dsRNA) notation meant to indicate an abbreviation (in which case, why is it bracketed by commas)? If the oligoribonucleotide consists of two separate strands, wherein there is a self-complementary structure, how can two

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separate strands be self-complementary and also be double stranded? It is unclear what the structure of the claimed oligoribonucleotide is.

Claim 224 and claims dependent on claim 224 are indefinite because the claim recites closed language, wherein the double stranded structure that consists of two RNA strands, but then recites further elements comprised in the double stranded structure later in the claim ("comprises a linker"). It is unclear how the double stranded structure can consist of two strands, but then comprise another element. Therefore, the scope of the claim is unclear.

Claim 237 and claims dependent on claim 237 are indefinite because the claim recites closed language, wherein the double stranded structure that consists of two RNA strands, but then recites further elements comprised in the double stranded structure later in the claim ("comprises a linker"). It is unclear how the double stranded structure can consist of two strands, but then comprise another element. Therefore, the scope of the claim is unclear.

Claim 249 is indefinite because it recites a double stranded structure full complementary to an RNA transcript. It is unclear how a double stranded structure (which requires two self complementary strands) can be fully complementary to an RNA transcript (which is single stranded). It seems only part of the double strand (one strand) could possibly be complementary to a transcript, and also be complementary to the other strand of the double stranded structure.

Claim 252 and claims dependent on claim 252 are indefinite because it is unclear what structure is being claimed. The claim recites an oligoribonucleotide that consists

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of various elements, but it is unclear what the elements are, for example, does the oligoribonucleotide consist of two separate RNA strands and a self-complementary double stranded structure and a dsRNA and a 3' overhang (which is not consistent with Applicant's arguments or specification), or does the oligoribonucleotide consist of the two separate RNA strands wherein the two strands consist of self-complementary double stranded structure and a dsRNA and a 3' overhang? Is there a double stranded structure and a dsRNA or is the (dsRNA) notation meant to indicate an abbreviation (in which case, why is it bracketed by commas)? If the oligoribonucleotide consists of two separate strands, wherein there is a self-complementary structure, how can two separate strands be self-complementary and also be double stranded? It is unclear what the structure of the claimed oligoribonucleotide is.

Claim 525 is indefinite because it recites a double stranded structure full complementary to an RNA transcript. It is unclear how a double stranded structure (which requires two self complementary strands) can be fully complementary to an RNA transcript (which is single stranded). It seems only part of the double strand (one strand) could possibly be complementary to a transcript, and also be complementary to the other strand of the double stranded structure.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 221-225, 232-239, 241-245 and 247-254 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Each of claims 221-225, 232-239, 241-245 and 247-254 are directed to dsRNA structures wherein the dsRNA comprises 3'-overhang, including a single base overhang, or to vectors and cells comprising said dsRNA. No support for a double stranded RNA structure comprising a 3'-overhang could be found in the originally filed specification or claims, therefore, this limitation is considered to be new matter. In the amendment filed March 7, 2003, Applicant argues support for the limitation of a 3'-overhang by making reference to Example 1, p 9-16 in the specification, however, this does not appear to support these limitations, particularly for the scope claimed. Applicant argues that the steps taken to make the dsRNA in Example 1 would result in a product that the skilled artisan would recognize as having a single base 3' overhang, due to the action of RNases added to the product, and, therefore, it supports the added limitation. This example, however, does not appear to do so. For example, Example 1 uses the RNases to eliminate all ssRNA in the mixture. Example 1 stresses the importance of this and provides controls to demonstrate that the digestion goes to completion. In this Example, the RNases used include RNase A, which cleaves after C's and U's (as argued by Applicant) and it is unclear why in a complete digestion of the

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RNA the bond between the UC at each end would not be cleaved. Even if this does not get cleaved, resulting in the one base overhang, this inherent characteristic of one embodiment in the specification would not provide support for the incredibly broad scope of the claimed oligoribonucleotides, for example, dsRNA's of a different sequence would not result in a similar overhang even if made using a similar method, nor is the support for putting this into a vector or a cell comprising such. The inherent characteristic present in this one example in the specification, wherein this characteristic was not even appreciated or pointed out by the inventor at the time of the invention, does not provide support for the broad scope of oligoribonucleotides now being claimed.

Claim Rejections - 35 USC § 102

The rejections of record under 35 USC 102 as anticipated by Alfonzo et al. and Kmiec et al. are withdrawn in response to Applicant's amendments.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (571) 272-0759. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Lacourciere
June 10, 2004


KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER